IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE SUBOXONE (BUPRENORPHINE HYDROCHLORIDE AND NALOXONE) ANTITRUST LITIGATION	**MDL NO. 2445** **13-MD-2445**
THIS DOCUMENT RELATES TO:, *Wisconsin, et al. v. Indivior Inc. et al.* Case No. 16-cv-5073	
STATE OF WISCONSIN **By Attorney General Brad D. Schimel, *et al.*** **Plaintiffs,** **v.** **INDIVIOR INC. f/k/a RECKITT BENCKISER PHARMACEUTICALS, INC., et al.** **Defendants.**	**CIV. A. NO. 16-5073**

Goldberg, J. **October 30, 2017**

MEMORANDUM OPINION

The Defendants in the present litigation—Indivior Inc., f/k/a Reckitt Benckiser Pharmaceuticals, Inc.; Reckitt Benckiser Healthcare (UK) Ltd.; Indivior PLC; and MonoSol Rx, LLC—each play some role in the manufacture, production, and/or sale of Suboxone, a medication that combines naloxone and buprenorphine to treat opioid addiction. Plaintiffs[1] have brought suit against Defendants alleging violations of federal and state antitrust statutes and state

[1] Plaintiffs are a collection of states, including the States of Wisconsin, Alabama, Alaska, Arkansas, California, Colorado, Connecticut, Delaware, Florida, Hawaii, Illinois, Iowa, Kansas, Louisiana, Maine, Maryland, Michigan, Minnesota, Mississippi, Missouri, Nebraska, New York, North Carolina, Ohio, Oklahoma, Rhode Island, South Carolina, Tennessee, Utah, Vermont, and Washington; the Commonwealths of Kentucky, Massachusetts, Pennsylvania, and Virginia; and the District of Columbia, by their Attorneys General (collectively, "Plaintiffs" or "States").

law unfair trade and consumer protection laws. Defendant MonoSol Rx ("Defendant" or "MonoSol") now moves to dismiss all claims against it. For the following reasons, I will deny the Motion in its entirety.

I. FACTUAL BACKGROUND[2]

A. General Background of Suboxone Tablet

In 2002, Indivior, Inc. ("Indivior")[3] introduced Suboxone, a drug designed for the treatment of opioid addiction, as a sublingual tablet. (Am. Compl. ¶¶ 33, 37.) At that time, the two component ingredients of Suboxone—naloxone and buprenorphine—were not subject to any patent protection. (Id.) In 1994, and in lieu of exclusivity through patent protection, the FDA granted Indivior's Suboxone tablets a seven-year period of exclusivity as an "orphan drug"[4] based on Indivior's representation that it would be unlikely to recover the costs of developing and marketing the drug. (Id. ¶¶ 34, 36–37.) Nonetheless, Suboxone did not obtain actual

[2] For a more comprehensive statement of the factual allegations underlying this lawsuit, I incorporate by reference my opinion in In re Suboxone (Buprenorphine Hydrochloride and Naloxone) Antitrust Litig., No. 16-5073, 2017 WL 3967911, at *1–6 (E.D. Pa. Sept. 8, 2017). For purposes of the present motion, however, I focus solely on MonoSol Rx LLC and the facts relevant to the issues before me. My recitation of the facts assumes the truth of the factual statements in the Amended Complaint. Fowler v. UPMC Shadyside, 578 F.3d 203, 211 (3d Cir. 2009).

[3] Indivior, Inc. ("Indivior) was formerly incorporated under the name of Reckitt Benckiser Pharmaceuticals, Inc. In December 2014, Reckitt Benckiser Pharmaceuticals, Inc. was demerged from its prior parent, the Reckitt Benckiser Group PLC, into Indivior PLC. (Am. Compl. ¶ 11.) Although the Amended Complaint uses the name "Reckitt" throughout the document, Indivior is now the proper name for this Defendant. To avoid confusion, I refer only to "Indivior" instead of "Reckitt."

[4] The FDA may designate a drug as an "orphan drug" when it determines that either (a) the drug is intended for the safe and effective, treatment, diagnosis or prevention of a rare disease or disorder that affects fewer than 200,000 people in the United States; or (b) the disease or disorder affects greater than 200,000, but the manufacturer is not reasonably expected to recover the costs of developing and marketing the treatment drug from sales in the United States. (Am. Compl. ¶ 35.) After designation as an orphan drug, the FDA approves the drug for marketing. (Id. ¶ 36.) It then becomes eligible for a seven-year exclusivity period during which it may be marketed as a brand-name drug free from generic competition. (Id.)

marketing exclusivity until 2002, thus allowing Indivior to market the Suboxone tablet until October 8, 2009, without the threat of competition from any generic co-formulated buprenorphine/naloxone tablet. (Id. ¶ 37.) Indivior allegedly earned more than $2 billion on Suboxone tablets by 2010. (Id. ¶ 38.)

As the orphan drug exclusivity period for Suboxone tablets neared expiration, Indivior became concerned that lower-priced generic versions of co-formulated buprenorphine/naloxone would enter the market and significantly reduce its sales and revenue of Suboxone tablets. (Id. ¶¶ 39, 42.) Faced with this impending loss of exclusivity, Indivior, in connection with Defendant MonoSol—a company specializing in PharmFilm technology—began to formulate a "Buprenorphine Generic Offensive Strategy." (Id. ¶¶ 44–45, 48.) This strategy relied on FDA regulations that allow branded manufacturers to seek FDA approval to modify the dosage form and strength of an existing product, which would in turn change its pharmaceutical equivalence and alter the AB-rating[5] of any proposed or available generic substitutes. (Id. ¶ 43.) The first step of the plan was to develop a new version of Suboxone which could be used to secure patent protection, while the second step was to convert the market for co-formulated

[5] Oral drugs proven to be both pharmaceutically equivalent and bioequivalent to a branded oral drug receive an "AB" rating from the FDA, indicating they are therapeutically equivalent to other drugs with the same rating in the same category. (Id. ¶ 30.) In most cases, only oral drugs with an AB rating may be substituted by pharmacists for a physician's prescription of a brand-name drug without the physician's approval. (Id.) The FDA publishes a list of all approved drugs and therapeutic equivalents in the Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"). (Id. ¶ 31.)

Once the FDA approves an ANDA and determines that the generic drug is AB-rated to the branded drug, state laws govern how the generic may be substituted for the brand name drug prescribed by physicians. (Id. ¶ 32.) In most states and under most health plans, a pharmacist may, and in many cases must, substitute an AB-rated generic drug for a prescribed brand-name drug. (Id. ¶ 32.)

buprenorphine/naloxone from Suboxone tablets to the newly-developed version of Suboxone. (Id. ¶ 45.)

B. The Creation and Marketing of Suboxone Film

In a December 2006 meeting, MonoSol and Reckitt Benckiser Healthcare UK Ltd. ("RBH"), Indivior's sister company, signed an agreement to develop and market a sublingual film form of Suboxone for the purpose of extending Indivior's exclusivity in the co-formulated buprenorphine/naloxone market. (Id. ¶ 46.) According to the Amended Complaint, MonoSol originally proposed this idea and convinced Indivior to develop the film product in partnership with MonoSol. (Id. ¶ 47.) Indeed, MonoSol encouraged Indivior and other pharmaceutical companies to engage in product hopping by advertising on its website, among other things, that "PharmFilm drug technology allows: no generic substitution," and "PharmFilm can be an ideal strategy for extending the life of a brand as generic incursion approaches." (Am. Compl. ¶ 48.) MonoSol also negotiated with Indivior to receive royalty payments on the sales of Suboxone film. (Id. ¶ 49.)

In April 2008, MonoSol applied for a patent, which was issued as patent number 8,017,150 entitled "Polyethylene Oxide-Based Films and Drug Delivery Systems Made Therefrom." (Id. ¶ 51.) Indivior listed the '150 patent, as well as patent numbers 8,475,832 and 8,603,514 in the FDA Orange Book, and alleged that they covered Suboxone film. (Id. ¶ 52.) The earliest patent expires in 2023. (Id.)

To speed up the approval process for the new film product, MonoSol suggested that Indivior have a pre-NDA filing guidance meeting with the FDA to request a priority review status. (Id. ¶ 53.) Both MonoSol and Indivior attended the FDA meeting. (Id.) MonoSol actively strategized with Indivior to minimize various manufacturing delays to beat generic

tablets to market. (Id. ¶ 54.) On October 28, 2008, Indivior submitted NDA 022410 to the FDA to market the sublingual film version of Suboxone. (Id. ¶ 55.) On August 21, 2009, the FDA rejected Indivior's application due to concerns that the film could be abused by patients and result in accidental exposure to children. (Id. ¶ 57.) In response, Indivior submitted a revised Risk Evaluation and Mitigation Strategy ("REMS")[6] to address the safety concerns related to the film form. (Id. ¶ 59.) Based on the REMS, the FDA approved Indivior's NDA for Suboxone film on August 30, 2010. (Id. ¶ 60.)

Because Suboxone film is in a different dosage form than Suboxone tablets, the two are not pharmaceutically equivalent. (Id. ¶ 56) Therefore, any tablet form of generic co-formulated buprenorphine/naloxone would not be an AB-rated generic substitute for Suboxone film. (Id.) According to the Amended Complaint, however, the film offers no significant benefits for patients over the tablet and any differences between the two formulations are "clinically insignificant." (Id. ¶ 62.) Moreover, the FDA found that the film has no demonstrable safety advantage over Suboxone tablets and, in fact, expressed concerns that the film actually presents increased safety issues and potential for abuse. (Id. ¶¶ 65–67.)

According to Indivior's Suboxone Reformulation Development Plan, its "Priority I" goal was "to keep the target moving to reduce generic competition." (Id. ¶ 69.) In a March 2007 email, Indivior explained that "the current plan calls for the introduction of the film in June 2009, transitioning [patients] from the [sublingual] tabs to the film, and then withdrawing the [sublingual] tabs altogether prior to October 2009." (Id. ¶ 70.) MonoSol made the original suggestion that the withdrawal of Suboxone tablets could provide further protection from generic

[6] The REMS is a document provided by the manufacturer and contains a risk management plan or risk-minimization strategy that goes beyond the professional labeling to ensure that the benefits of a drug outweigh the risk. (Id. ¶ 58.)

entry into the market, and this plan was discussed with employees of Reckitt Benckiser Healthcare, Ltd. (Id. ¶ 71.)

Subsequently, Indivior engaged in a multi-faceted campaign to convert the co-formulated buprenorphine/naloxone market to Suboxone film. (Id. ¶ 72.) First, Indivior communicated to the public and the medical community that single-dose or unit-dose packaging was necessary to prevent potential exposure to multiple doses in the case of accidental pediatric exposure, and it began marketing Suboxone film in unit-dose packaging. (Id. ¶ 74.) In connection with this message, it partnered with consulting firm Venebio Group, LLC to develop its "Film is safer" platform, which it acknowledged was due solely to "packaging type." (Id. ¶ 75.) Although Suboxone tablets had been sold in unit-dose packaging outside of the United States since 2005, Indivior did not make any attempt to convert its tablet packaging in the United States to unit-dose packaging, but rather continued to sell tablets in multi-unit bottles. (Id. ¶ 76.)

Second, Indivior began a "multi-front offensive" to get film into the market before the generics could enter with their version of the tablet, including (1) aggressively promoting the alleged superiority of the film to doctors, payors and pharmacists; (2) encouraging use of the film through a targeted and sustainable payor strategy by creating a patient subsidy program available only for Suboxone film; (3) pricing film to be less expensive than tablets despite the more expensive production costs for film; (4) hiring and compensating its sales force so that it would earn bonuses for convincing health care providers to convert to film; and (5) coordinating efforts among field sales, marketing, and government to drive film's "stickiness" with targeted payors. (Id. ¶¶ 77–80, 83–86.)

In September 2012, Indivior issued a press release advising the public and prescribing physicians that it intended to withdraw the tablets from the market within the next six months

due to a "pediatric exposure safety issue." (Id. ¶ 81.) Indivior also sought an FDA declaration that Suboxone tablets were being voluntarily pulled from the market for safety concerns. (Id. ¶ 82.) For its part, MonoSol engaged in numerous conversations with Indivior about film pricing and made adjustments to its own costs to ensure profitability to both Indivor and itself on Suboxone film, despite the fact that it was launched at a lower price point. (Id. ¶ 85.) By mid-2012, the film accounted for over seventy percent of Suboxone prescriptions. (Id. ¶ 87.) By the time the generic tablets received FDA approval in February 2013, eighty-five percent of Suboxone prescriptions were written for film. (Id.) Indivior withdrew Suboxone tablets from the market on March 18, 2013. (Id. ¶ 88.)

C. The Plan to Delay Generic Entry

The orphan drug exclusivity on branded Suboxone tablets expired on October 8, 2009, and ANDAs for approval to sell generic Suboxone tablets were filed in late 2009. (Id. ¶ 89.) Nevertheless, generic buprenorphine/naloxone tablets did not gain FDA approval until February 2013. (Id. ¶ 89.)

In late 2011, while certain potential generic competitors were awaiting FDA approval of their ANDAs, Indivior submitted a REMS for Suboxone tablets, which was approved by the FDA in December 2011. (Id. ¶ 90.) On January 6, 2012, the FDA ordered Indivior to cooperate with its potential competitors—including Actavis, Inc., Amneal Pharmaceutical LLC, Ethypharm USA Corp., Mylan Inc., Roxane Laboratories Inc., Sandoz Inc., Sun Pharmaceuticals Industries, Ltd., and Teva Pharmaceuticals USA, Inc. (collectively, the "Buprenorphine Products Manufacturers Group")—in a shared REMS. (Id. ¶ 91.) Shared REMS, like individual REMS, are used to address safety concerns of pharmaceutical products, but are designed to cover the

situation where multiple manufacturers are marketing a generic product that is an AB-rated substitute product for a referenced drug. (Id.)

Despite the fact that Indivior's Suboxone tablet REMS had just been approved by the FDA in December 2011, Indivior allegedly did not cooperate with the generic manufacturers in the finalization and submission of a shared REMS. (Id. ¶ 93.) While not explicitly refusing to participate, it engaged in multiple delay tactics to prolong the approval of the ANDA for the generics. (Id.) Indivior's refusal to cooperate successfully delayed submission of the shared REMS until August of 2012, when the generic ANDA filers obtained a waiver allowing them to submit a shared REMS program of their own without Indivior's cooperation. (Id. ¶ 97.)

In another purported delay tactic, Indivior filed a citizen petition[7] with the FDA on September 25, 2011. (Id. ¶ 98.) MonoSol actively participated in this process, holding "urgent" meetings with Indivior to explore possible citizen petition opportunities regarding Suboxone tablets. (Id. ¶ 112.) Indivior's citizen petition asked the FDA to withhold approval of the ANDAs for generic Suboxone tablets unless: (1) the ANDA contained a targeted pediatric exposure education program; (2) the ANDA product had child-resistant unit-dose packaging; and (3) the FDA had determined whether Indivior had discontinued Suboxone tablets for safety reasons. (Id. ¶ 102.)

In the same week it filed the citizen petition, Indivior announced its intent to permanently withdraw Suboxone tablets from the market for safety reasons. (Id. ¶ 103.) Indivior never

[7] Under § 505 of the Food, Drug and Cosmetic Act, any individual may submit a "citizen petition" asking the FDA to take, or refrain from taking, certain administrative action. (Id. ¶ 99.) Such petitions are commonly used to express concerns about the safety or legality of a product. (Id.) Pursuant to 21 C.F.R. § 10.30, the FDA then has 150 days to respond to the citizen petition. (Id. ¶ 100.) During that period, FDA approval of any ANDA pending for the subject product is typically delayed, leading to some abuse by brand-name manufacturers in filing baseless citizen petitions in order to prolong their monopolies. (Id. ¶ 101.)

disclosed these alleged safety concerns about Suboxone tablets to the generic manufacturers during the shared REMS negotiation process. (Id. ¶ 104.) Moreover, one month prior, on August 30, 2012, Indivior specifically represented to the FDA, in a REMS assessment, that its tablet was successful, it needed no further changes, and Indivior had considered and rejected converting its Suboxone tablets to unit-dose packaging for pediatric safety reasons. (Id. ¶ 105.)

The FDA denied Indivior's citizen petition on February 22, 2013, noting the petition was not supported by evidence and was inconsistent with Indivior's own behavior. (Id. ¶ 108.) The FDA further acknowledged that it had no authority to require Suboxone ANDAs to contain targeted pediatric exposure labeling because, pursuant to 21 U.S.C. § 355(j)(2)(A)(v) and 4(G), the labeling for an ANDA must be the same as the labeling for the approved listed drug. (Id. ¶ 108.) The FDA also stated that the close proximity of Indivior's withdrawal of Suboxone tablets to the "period in which generic competition for this product was expected to begin cannot be ignored." (Id. ¶ 109.) In turn, the FDA referred Indivior's conduct to the Federal Trade Commission for antitrust investigation. (Id. ¶ 110.) Despite the denial, the citizen petition nonetheless had the effect of delaying FDA approval of the pending ANDAs. (Id. ¶¶ 111, 113.)

On February 22, 2013, the FDA granted the generics-only, waiver-based REMS and approved Amneal's and Activis's ANDAs for tablet sales. (Id. ¶ 114.) On March 6, 2013, generic co-formulated buprenorphine/naloxone tablets entered the market. (Id. ¶ 115.)

D. Procedural History

In June 2013, several putative classes initiated litigation against the various Defendants alleging anticompetitive behavior with respect to the marketing and sale of Suboxone. These cases were consolidated into a multi-district litigation ("MDL") in this Court. Among those matters was the class action complaint brought by Direct Purchaser Plaintiffs and End-Payor

Plaintiffs alleging that Defendants unlawfully delayed and impeded competition from generic versions of Suboxone tablets, resulting in ongoing overpayments by consumers. On December 3, 2014, I issued an opinion allowing most of the federal and state law claims to proceed, but dismissing one of Direct Purchaser Plaintiffs' stand-alone antitrust claims, a variety of state law claims by the End-Payor Plaintiffs, and claims against several of the other Defendant entities. In re Suboxone, 64 F. Supp. 3d 665 (E.D. Pa. 2014).

On December 23, 2015, Amneal Pharmaceuticals LLC ("Amneal"), a generic manufacturer and competitor of Indivior, filed a complaint regarding Indivior's alleged anticompetitive conduct with respect to Suboxone. That case was consolidated with the MDL currently before me. On January 4, 2017, I issued a decision dismissing only part of Amneal's claims against Indivior. In re Suboxone, 13-MD-2445, 2017 WL 36371 (E.D. Pa. Jan. 4, 2017).

On September 22, 2016, the Plaintiff States initiated the current litigation against Defendants, and the case was consolidated with the MDL. The States filed a First Amended Complaint on November 23, 2016, setting forth five causes of action as follows:
(1) monopolization under the Sherman Act § 2 against Indivior, I-PLC, and RBH; (2) attempted monopolization under the Sherman Act § 2 against Indivior, I-PLC, and RBH; (3) conspiracy to monopolize under the Sherman Act § 2 against all Defendants; (4) illegal restraint of trade under the Sherman Act § 1 against all Defendants; and (5) individual state law claims against all Defendants. Several motions, filed pursuant to Federal Rule of Civil Procedure 12(b)(6) followed, including the motion before me filed by MonoSol.

On September 8, 2017, I denied Indivior's Motion to Dismiss these claims and found that the Amended Complaint adequately alleged an anticompetitive product-hopping scheme and related conspiracy by Indivior. In re Suboxone Antitrust Litig., No. 16-5073, 2017 WL 3967911,

at *1–6 (E.D. Pa. Sept. 8, 2017). Subsequently, on October 17, 2017, I granted RBH's Motion to Dismiss. In re Suboxone Antitrust Litig., No. 16-5073, 2017 WL 4642285 (E.D. Pa. Oct. 17, 2017). Subsequently, on October 25, 2017, I granted I-PLC's Motion to Dismiss. In re Suboxone Antitrust Litig., No. 16-5073, 207 WL 4810801 (E.D. Pa. Oct. 25, 2017).

On December 12, 2016, MonoSol filed a motion to dismiss the Amended Complaint. The States responded on January 30, 2017, and MonoSol filed a reply brief on February 21, 2017.

II. STANDARD OF REVIEW

Under Federal Rule of Civil Procedure 12(b)(6), a defendant bears the burden of demonstrating that the plaintiff has not stated a claim upon which relief can be granted. Fed. R. Civ. P. 12(b)(6); see also Hedges v. United States, 404 F.3d 744, 750 (3d Cir. 2005). The United States Supreme Court has recognized that "a plaintiff's obligation to provide the 'grounds' of his 'entitle[ment] to relief' requires more than labels and conclusions." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007) (quotations omitted). "[T]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice" and "only a complaint that states a plausible claim for relief survives a motion to dismiss." Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Id. A complaint does not show an entitlement to relief when the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct. Id.

The United States Court of Appeals for the Third Circuit has detailed a three-step process to determine whether a complaint meets the pleadings standard. Bistrian v. Levi, 696 F.3d 352 (3d Cir. 2014). First, the court outlines the elements a plaintiff must plead to state a claim for

relief. Id. at 365. Next, the court must "peel away those allegations that are no more than conclusions and thus not entitled to the assumption of truth." Id. Finally, the court "look[s] for well-pled factual allegations, assume[s] their veracity, and then 'determine[s] whether they plausibly give rise to an entitlement to relief.'" Id. (quoting Iqbal, 556 U.S. at 679). The last step is "a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." Id. (quoting Iqbal, 556 U.S. at 679).

III. DISCUSSION

The claims against MonoSol involve allegations of a conspiracy to monopolize under the Sherman Act § 2, illegal restraint of trade under Sherman Act § 1, and various state law causes of action. Moving to have all claims against it dismissed, MonoSol sets forth six general arguments: (1) the Amended Complaint does not plausibly allege that MonoSol participated in an unlawful, anticompetitive agreement; (2) the Amended Complaint does not adequately plead proximate causation; (3) the Amended Complaint fails to adequately plead a relevant market; (4) the Amended Complaint does not plausibly plead that MonoSol possessed the requisite specific intent for a Sherman Act § 2 claim; (5) the claims against MonoSol are time barred; and (6) the state law claims must be dismissed for the same reasons as the federal law claims.

A. Whether the Amended Complaint Plausibly Alleges that MonoSol Participated in an Unlawful Anticompetitive Agreement

"To prevail on a section 1 claim or a section 2 conspiracy claim, a plaintiff must establish the existence of an agreement, sometimes also referred to as a 'conspiracy' or 'concerted action.'"[8] W. Penn Allegheny Health System, Inc. v. UPMC, 627 F.3d 85, 99 (3d Cir. 2010)

[8] A Section 2 conspiracy claim has four elements: (1) an agreement to monopolize; (2) an overt act in furtherance of the conspiracy; (3) a specific intent to monopolize; and (4) a causal connection between the conspiracy and the injury alleged. Howard Hess Dental Labs. Inc. v. Dentsply Int'l, Inc., 602 F.3d 237, 253 (3d Cir. 2010) (citing United States v. Yellow Cab Co.,

(quoting Twombly, 550 U.S. at 553; Gordon v. Lewistown Hosp., 423 F.3d 184, 207 & n.16 (3d Cir. 2005)). "An agreement exists when there is a unity of purpose, a common design and understanding, a meeting of the minds, or a conscious commitment to a common scheme." Id. (citing Copperweld Corp. v. Indep. Tube Corp., 467 U.S. 752, 771 (1984); Howard Hess Dental Labs., Inc. v. Dentsply Int'l Inc., 602 F.3d 237, 254 (3d Cir. 2010); Gordon, 423 F.3d at 208). To plead an agreement, a plaintiff may allege direct or circumstantial evidence, or a combination of the two. Id.

In support of their claim that MonoSol and Indivior had an agreement, Plaintiffs allege that "[d]efendants Reckitt [consisting of all of the Defendant Reckitt entities] and MonoSol conspired to monopolize the relevant market for co-formulated buprenorphine/naloxone products." (Am. Compl. ¶ 149.) According to Plaintiffs, Reckitt Benckiser Healthcare UK, Ltd. and MonoSol "entered into a development agreement whereby MonoSol granted [Indivior] the right to use its patented sublingual film technology to manufacture Suboxone in a film version." (Id. ¶ 150.) MonoSol actually convinced Indivior to introduce the Suboxone film as a means of preserving Indivior's market share and market exclusivity. (Id. ¶¶ 47–50.) Plaintiffs go on to contend that MonoSol and Indivior thereafter worked jointly to develop the Suboxone film, obtain a patent, and bring the final product to market prior to the entry of generic co-formulated buprenorphine/naloxone tablets. (Id. ¶¶ 50–54.) MonoSol then made the initial suggestion that Indivior's "withdrawal of Suboxone tablets from the market could provide further protection from generic incursion," "engaged in numerous conversations with [Indivior] about Film

---

332 U.S. 218, 224–25 (1947); Am. Tobacco Co. v. United States, 328 U.S. 781, 788, 809 (1946)). "A plaintiff asserting a Section 1 claim also must allege four elements: '(1) concerted action by the defendants; [(2)] that produced anti-competitive effects within the relevant product and geographic markets; (3) that the concerted actions were illegal; and (4) that it was injured as a proximate result of the concerted action.'" Id. (quoting Gordon v. Lewistown Hosp., 423 F.3d 184, 207 (3d Cir. 2005)).

pricing," and "made adjustments to its own costs to ensure profitability to [Indivior] and MonoSol on Suboxone Film, despite the fact that it was launched at a lower price point to encourage the product switch." (Id. ¶¶ 71, 85.) Finally, it alleged that MonoSol "actively participated in [Indivior's] plan to delay generic entry through its abuse of the citizen petition process." (Id. ¶ 112.) Ultimately, the Amended Complaint concludes that "[Indivior] and MonoSol entered into the agreement with the specific intent and for the purpose of extending [Indivior's] monopoly power, which was due to expire at the end of [Indivior's] FDA-granted 'orphan status' period, and for the purpose of preventing generic competition with its branded product." (Id. ¶ 152.)

MonoSol now contends that these allegations are insufficient to plead an anticompetitive agreement because: (1) MonoSol and Indivior cannot, as a matter of law, conspire with each other; (2) any agreement to develop and introduce a new product is pro-competitive and, thus, not barred by the Sherman Act; and (3) Plaintiffs have not adequately pled facts to support the inference that MonoSol engaged in exclusionary conduct.

1. Whether MonoSol and Indivior Can Conspire as a Matter of Law

MonoSol's first argument relies upon the single-entity doctrine set forth in Copperweld Corp. v. Independence Tube Corp., 467 U.S. 752 (1984), which holds that a parent and its wholly-owned subsidiary are a single entity incapable of conspiring. MonoSol reasons that courts have applied the single-entity doctrine of Copperweld to a wide range of corporate relationships, including (a) situations involving a joint venture between two entities and (b) where the relationship between the two entities was one of patent holder and exclusive licensee. MonoSol concludes that both of these scenarios apply here and establish that MonoSol

and Indivior are a single economic unit that could not have conspired for purposes of a Sherman Act conspiracy claim.

With respect to MonoSol's theory that the two companies were in a joint venture in which MonoSol was effectively the agent of Indivior, I considered this identical argument in my Memorandum and Order on Defendant Indivior, Inc.'s Motion to Dismiss. As here, the defendant relied on Siegel Transfer, Inc. v. Carrier Express, Inc., 54 F.3d 1125, 1133 (3d Cir. 1995) to argue that a company and its agents acting jointly for a common purpose could not conspire. Rejecting this extension of Copperweld, I held that:

> The Third Circuit in Siegel Transfer relied heavily on the fact that Oak Management constituted "an inseparable part of Carrier Express' structure" because it handled all of Carrier Express' day-to-day operations, its economic success was tied to Carrier Express' success because it received a percentage of Carrier Express' revenue, and it did not compete with Carrier Express. In stark contrast, MonoSol is a separate corporation engaged in the development, manufacture and sale of pharmaceuticals throughout the United States. (Am. Compl. ¶ 14.) Neither Indivior nor MonoSol were responsible for the other corporation's day-to-day operations. Moreover, although Indivior contracted for MonoSol to receive royalty fees on sales of Suboxone film, nothing in the complaint suggests that this was MonoSol's sole form of income or that its economic success was tied fully to Indivior's economic success. Rather, the reasonable inference is that the particular agreement between the two parties created economic incentives for the parties to put forth their best faith efforts in carrying out their joint venture related to Suboxone film. On a broader scale, the two parties were acting for their own financial interests. See Am Needle, 560 U.S. at 201 ("If the fact that potential competitors shared in profits or losses from a venture meant that the venture was immune from § 1, then any cartel 'could evade the antitrust law simply by creating a "joint venture" to serve as the exclusive seller of their competing products.'") (citations omitted).
>
> Finally, the Amended Complaint allows the reasonable inference that MonoSol could have competed in the relevant market outside of its agreement with Indivior. MonoSol purportedly encouraged Indivior "and other pharmaceutical companies" to partner with MonoSol and use its "PharmFilm formulations" to "introduce

> products that are highly differentiated from other dosage forms, both in performance and marketability, creating fresh, dynamic revenue-creating opportunities." (Id. ¶ 48.) Indivior was but one of the companies to enter into such an agreement with MonoSol. (Id. ¶ 49.) In short, the relationship between Indivior and MonoSol "is one of competitive reality" lacking "complete unity of interest," and does "not possess either the unitary decisionmaking quality or the single aggregation of economic power characteristic of independent action." Am. Needle, 560 U.S. at 195.

In re Suboxone, No. 16-5073, 2017 WL 3967911, at * 21 (E.D. Pa. Sept. 8, 2017). As I find that discussion to comprehensively address MonoSol's current argument, I adopt it in full with respect to MonoSol's Motion to Dismiss.[9]

I likewise reject MonoSol's second theory that MonoSol and Indivior were a single economic entity as patent licensor and licensee with respect to the Suboxone film. Numerous courts within this and other districts have found that where the alleged anticompetitive behavior "is purely derivative of the legal patent monopoly and legal exclusive distributorship," there can be no claim for an antitrust conspiracy. Sheet Metal Duct, Inc. v. Lindab, Inc., No. 99-6299,

[9] In further support of its argument, MonoSol cites to several other cases that I did not previously address. First, it relies on Deutscher Tennis Bund v. ATP Tour, Inc., 610 F.3d 820, 834–35 (3d Cir. 2010) for the blanket proposition that Copperweld applies to joint ventures of separately-owned entities. In that case, however, the court expressly acknowledged that "the fact that joint venturers pursue the common interest of the whole is generally not enough, by itself, to render them a single entity." Id. at 835 (quotation omitted).

MonoSol also cites to Peerless Heater Co. v. Mestek, Inc., No. 98-6532, 2000 WL 637082 (E.D. Pa. May 11, 2000). In Peerless, however, the court found that the corporation was not capable of conspiring with its own sales agents or representatives in restraint of trade. Id. at *6. By contrast, in this case, Indivior and MonoSol are entirely separate corporations with independent economic structures and separate centers of decisionmaking that were jointly pursuing a common interest.

Finally, MonoSol cites Texaco, Inc. v. Dagher, 547 U.S. 1, 4 (2006) for the proposition that it is not per se illegal under § 1 of the Sherman Act for a lawfully integrated venture to set the prices at which it sells its products. That case neither applied Copperweld nor found that two companies engaged in a joint venture could not conspire to monopolize by engaging in various anticompetitive acts under § 2 of the Sherman Act.

2000 WL 987865, at *6 (E.D. Pa. July 18, 2000) (holding that where patentee sells its product exclusively to licensee at lower price, and where plaintiff must obtain product from licensee at higher price than if it bought directly from patentee, no antitrust violation exists given the "fundamental legitimacy of the exclusive distributorship arrangement for the patented product"); see also Shionogi Pharma, Inc. v. Mylan, Inc., No. 10-1077, 2011 WL 2174499, at *5 (D. Del. May 26, 2011) (dismissing conspiracy claim because the complaint inadequately pled a plausible conspiracy and because of the relationship between the alleged conspirators as exclusive licensee and patent holder which gave them unified interests); Levi Case Co., Inc. v. ATS Prods., Inc., 788 F. Supp. 428, 432 (N.D. Cal. 1992) (holding that where a patentee conveyed an exclusive licensee in three patents to a licensor who executed a sublicense with a sub-licensor, the patentee and sub-licensor "were not independent sources of economic power" and did not have "any independent decisionmaking authority regarding the exploitation of the patent"). In all of these cases, the alleged antitrust conduct involved the use of the patent by the licensee after the license had been granted, thereby preventing any finding of concerted activity or common design to commit an antitrust violation. See Sheet Metal Duct, 2000 WL 987865, at *1; Shionogi, 2011 WL 2174499, at *1; Levi Case, 788 F. Supp. at 431–32.

In stark contrast to these cases, the patentee/licensee relationship in this case is ancillary to the anticompetitive conduct at the heart of the alleged conspiracy. As set forth above, MonoSol, aware of Indivior's pending loss of exclusivity on its Suboxone tablet, approached Indivior about developing Suboxone film for the purpose of extending Indivior's exclusivity in the co-formulated buprenorphine/naloxone market. (Am. Compl. ¶ 46.) The two companies then allegedly entered into an agreement in which they would jointly develop the film and MonoSol would receive royalty fees on the sales of the film. (Id. ¶ 49.) Subsequent to that

agreement, MonoSol applied for the patent on Indivior's behalf and the two companies strategized to minimize manufacturing delays. (Id. ¶¶ 51–54.) MonoSol then allegedly suggested that Indivior withdraw Suboxone tablets from the market in order to convert the market from tablets to film, made adjustments to its own costs to ensure that the film could be launched at a lower price point, and participated in Indivior's plan to delay generic entry by helping Indivior explore what citizen petition opportunities may exist regarding Suboxone tablets. (Id. ¶¶ 71, 85, 112.) The mere fact that this overall scheme included the existence of an exclusive license relationship between Indivior and MonoSol neither puts this case on par with those cited above or brings it within the realm of the Copperweld doctrine. Rather, the Amended Complaint describes two separate entities that engaged in concerted action to jointly advance their independent economic interests.

In short, I find that the Copperweld doctrine does not apply in this case such that MonoSol and Indivior may be viewed as a single economic entity.

2. Whether an Agreement to Develop and Introduce a New Product is Pro-Competitive

Alternatively, MonoSol argues that the Amended Complaint does not allege facts demonstrating that its participation in the development and manufacture of Suboxone film was anticompetitive. It contends that introducing a new product is an inherently pro-competitive activity and can only be deemed otherwise when the product introduction is accompanied by additional coercive conduct that forecloses the market from competition. According to MonoSol, mere allegations that a new product is inferior to existing products or that the seller of the new product sought to attract customers by encouraging a switch away from existing products are insufficient to establish anticompetitive conduct.

I have previously rejected this argument in connection with my ruling on Indivior's Motion to Dismiss. Although "simply introducing a new product on the market, whether it is a superior product or not, does not, by itself, constitute exclusionary conduct," I previously held that "[t]he key question is whether the defendant combined the introduction of a new product with some other wrongful conduct, such that the comprehensive effect is likely to stymie competition, prevent consumer choice and reduce the market's ambit." In re Suboxone, 2017 WL 3967911, at *22 (quoting In re Suboxone, 64 F. Supp. 3d 665, 682 (E.D. Pa. 2014)). "Product innovation generally benefits consumers and inflicts harm on competitors, so courts look for evidence of 'exclusionary or anticompetitive effects' in order to 'distinguish "between conduct that defeats a competitor because of efficiency and consumer satisfaction"' and conduct that impedes competition through means other than competition on the merits." New York ex rel. Schneiderman v. Actavis PLC, 787 F.3d 638, 652 (2d Cir. 2015). Thus, when a monopolist combines product improvement with some other conduct, the overall effect of which is to coerce consumers rather than persuade them on the merits, the conduct is anticompetitive under the Sherman Act. Id. at 653–54.

Applying these principles to the present facts, I found:

> Had Plaintiffs limited their allegations regarding the conspiracy between Indivior and MonoSol to mere product innovation and introduction of the Suboxone film, Plaintiffs would have been hard-pressed to establish that the conspiracy acted in restraint of trade or for a noncompetitive purpose. Contrary to Defendant's arguments, however, the Amended Complaint goes far beyond allegations that the "conspiracy" was intended only to introduce a new product into the market; rather it combines allegations of product improvement with product withdrawal and other anticompetitive conduct.
>
> . . .
>
> Considered collectively, [the Amended Complaint's allegations] plausibly plead that the conspiracy between MonoSol and Indivior

> was designed squarely to "stymie competition, prevent consumer choice and reduce the market's ambit." Suboxone, 64 F. Supp. 3d at 682.

In re Suboxone, 2017 WL 3967911, at *22.

While MonoSol, much like Indivior, attempts to argue that the true purpose of the joint venture was pro-competitive innovation, the "rule of reason" burden-shifting framework set forth in United States v. Microsoft Corp., only requires a plaintiff, at the pleading stage, to allege the anticompetitive nature of a defendant's conduct. 253 F.3d 34, 58 (D.C. Cir. 2001). Taking the allegations of the Amended Complaint as true, I find that Plaintiffs sufficiently alleged anticompetitive conduct against MonoSol.

3. Whether Plaintiffs Adequately Pled Facts Supporting the Inference that MonoSol Engaged in Exclusionary Conduct

MonoSol also contends that the Amended Complaint is devoid of allegations that it participated in exclusionary conduct. MonoSol argues that Plaintiffs' allegations against it center on (1) its efforts to market its film technology as a differentiator for products going off patent; (2) its efforts to reduce costs and accelerate production of Suboxone film; (3) the fact that film sales would rise if there were no tablets on the market; and (4) unspecified discussions with Indivior about a potential citizen's petition. (Def.'s Mem. Supp. Mot. to Dismiss 15.) MonoSol then goes on to individually address each of these types of conduct, ascribing non-competitive motives to each of its actions and minimizing the extent of its involvement in the alleged anticompetitive scheme spearheaded by Indivior.

MonoSol's argument improperly attempts to discredit each of the foregoing actions in isolation without addressing the plausible inferences that may be drawn at this stage of the case from the actions considered collectively. As noted above, "[c]oncerted action" consists of "two or more distinct entities . . . agree[ing] to take action against the plaintiff," Gordon v. Lewistown

Hosp., 423 F.3d 184, 207 (3d Cir. 2005) (citations omitted), such that "the alleged conspirators had a unity of purpose or a common design and understanding, or a meeting of the minds." Toledo Mack Sales & Serv., Inc. v. Mack Trucks, Inc., 530 F.3d 204, 219 (3d Cir. 2008) (quotation and citation omitted). Participation in a conspiracy under § 1 does not depend on "any overt act other than the act of conspiring . . ., [i.e.] aid[ing] or assist[ing] in carrying out the purposes of the conspiracy." Tunis Bros. Co., Inc. v. Ford Motor Co., 763 F.2d 1482, 1491 (3d Cir. 1985), vacated and remanded on other grounds, 475 U.S. 1105 (1986). Therefore, when pleading a Sherman antitrust conspiracy claim, the plaintiffs "must make allegations, taken as true, supporting a plausible inference that [a defendant] participated in the alleged conspiracy. To do this, [the plaintiffs] need not necessarily provide any particular details about conduct undertaken by [the defendant] in furtherance of the conspiracy." Hinds Cnty., Miss. v. Wachovia Bank N.A., 700 F. Supp. 2d 378, 395 (S.D.N.Y. 2010). Rather, the allegations must raise the plausibility of a defendant's participation in the alleged conspiracy "above the speculative level" and create the "reasonably founded hope that the [discovery] process will reveal relevant evidence to support a § 1 claim." Id. at 396 (quoting Twombly, 550 U.S. at 559) (internal quotation marks omitted).

The allegations of the Amended Complaint permit such a plausible inference. As set forth above, the alleged product-hopping scheme at issue in this case involves Defendants' introduction of a new film version of Suboxone on the brink of the loss of patent exclusivity of the Suboxone tablet, the subsequent withdrawal of the tablet from the market, disparagement of the safety and efficacy of the tablet, and efforts to delay the entry of generic tablets by failing to cooperate in a shared REMS process and filing a sham citizen petition against the generic tablets. According to the Amended Complaint, MonoSol participated in this scheme in multiple respects.

Primarily, it approached Indivior with the plan to file a new drug application to market Suboxone in a sublingual film form purposely to extend Indivior's exclusivity in the co-formulated buprenorphine/naloxone market. (Am. Compl. ¶¶ 46, 48.) MonoSol then allegedly negotiated with Indivior to receive royalty payments on sales of Suboxone film, applied for the patent on Indivior's behalf, and actively strategized with Indivior to minimize manufacturing delays, all of which indicated its involvement in some concerted action with Indivior. (Id. ¶¶ 49, 51, 54, 61.) The Amended Complaint explains that, in an effort to convert the market for the purpose of ensuring the film's dominance in the market, MonoSol explicitly suggested to Indivior that it make the "hard switch" from tablets to film—*i.e.*, withdraw the Suboxone tablet from the market. (Id. ¶¶ 71, 73, 85.) Finally, MonoSol allegedly participated in meetings with Indivior about possible citizen petition possibilities to delay entry of generic tablets. (Id. ¶ 112.) Reading these allegations collectively, and in the light most favorable to Plaintiffs, I find that Plaintiffs have created a plausible inference that MonoSol participated in the alleged conspiracy.[10]

B. Whether the Amended Complaint Adequately Pleads Proximate Causation

MonoSol next contends that Counts III and IV of the Amended Complaint should be dismissed because Plaintiffs do not adequately allege that MonoSol's conduct proximately cause their injuries. Given the fairly liberal pleading standards with respect to antitrust injury, I must disagree.

[10] Via a footnote in its brief, MonoSol argues that Plaintiffs fail to allege acts that MonoSol took in furtherance of a Section 2 conspiracy because there are no claims against MonoSol for monopolization or attempted monopolization. It is well established, however, that claims of monopolization or attempted monopolization require that the defendant itself compete directly in a certain market, whereas a claim of conspiracy to monopolize requires only that a company agree with another company to assist the first in its attempt to monopolize the relevant market. Arnold Chevrolet LLC v. Tribune Co., 418 F. Supp. 2d 172, 185 (E.D.N.Y. 2006). In other words, a defendant need not be liable for monopolization or attempted monopolization in order to be liable for a section 2 claim for conspiracy to monopolize.

The plaintiffs in any antitrust case "must prove antitrust injury, which is to say (1) injury of the type the antitrust laws were intended to prevent and (2) that flows from that which makes defendants' acts unlawful." A.D. Bedell Wholesale Co. v. Philip Morris Inc., 263 F.3d 239, 247 (3d Cir. 2001) (quoting Brunswick Corp. v. Pueblo Bowl–O–Mat, 429 U.S. 477, 489 (1977) (emphasis omitted)). A plaintiff "need not allege proximate cause or antitrust injury separately for each component of the alleged scheme. . . [rather] [t]he injuries inflicted by [the defendant's] allegedly anticompetitive activities should, instead, be viewed as a whole." In re Gabapentin Patent Litig., 649 F. Supp. 2d 340, 355–56 (D.N.J. 2009) (citing Biovail Corp. Int'l v. Hoechst Aktiengesellschaft, 49 F. Supp. 2d 750, 767 (D.N.J. 1999) (holding that antitrust injury is determined by anticompetitive conduct as a whole and such analysis will be conducted when it is established that an antitrust violation has been pleaded)). Notably, "the existence of antitrust injury is not typically resolved through motions to dismiss." Schuylkill Energy Res., Inc. v. Pa. Power & Light Co., 113 F.3d 405, 417 (3d Cir. 1997) (citing Brader v. Allegheny Gen. Hosp., 64 F.3d 869, 876 (3d Cir. 1995)); see also In re Wellbutrin SR/Zyban Antitrust Litig., 281 F. Supp. 2d 751, 757 (E.D. Pa. 2003) (denying motion to dismiss antitrust claims for lack of antitrust injury because "Plaintiffs may be able to prove that the allegedly frivolous lawsuits 'materially caused' their alleged injuries.").

Crucially, a plaintiff need not assert that the defendant's anticompetitive actions were the sole cause of its injury. Gabapentin, 649 F. Supp. 2d at 356 (citing Zenith Radio Corp. v. Hazeltine Research, Inc., 395 U.S. 100, 114 n.9 (1969) (noting that an antitrust plaintiff may establish antitrust injury with "proof of some damage flowing from the unlawful conspiracy; inquiry beyond this minimum point goes only to the amount and not the fact of damage."). Nor must a plaintiff "completely discredit in its initial pleadings all possible intervening causes" of its

injury. Id. at 346. Rather, a plaintiff need only show that a violation is a "material cause" of the claimed injury. Zenith Radio, 395 U.S. at 114 n.9. Otherwise, "to require proof that the illegal conduct was the *exclusive* cause of the plaintiff's injury would effectively deny private remedies, because multiple causes always affect everyone." 2 Phillip E. Areeda & Herbert Hovenkamp, Antitrust Law ¶ 338a at 317 (2d Ed. 2000).

The Amended Complaint in this case pleads injury and causation as follows:

> 118. Reckitt's conspiracy with MonoSol and its acts, practices, and scheme described herein were for the purposes of, and had the effect of restraining competition unreasonably by preventing the entry of generic co-formulated buprenorphine/naloxone and destroying the market for the tablet formulation by the time the generic competitors gained FDA approval.
>
> 119. But for Reckitt and MonoSol's illegal conduct, generic competition to Suboxone Tablets would have been available after orphan exclusivity expired in October, 2009. Thus, Defendants' conduct delayed and prevented the savings that Suboxone purchasers would have enjoyed from that point until present date.
>
> . . .
>
> 121 Had generic competition to Suboxone Tablets entered the market earlier—and not been delayed while Defendants converted the market to Suboxone Film—government entities and consumers would have substituted lower-priced generic Suboxone Tablets for the higher-priced branded Suboxone Tablets, and would have paid lower prices for some or all of their branded Suboxone purchases.
>
> . . .
>
> 123. By delaying generic competitors' entry into the market, Reckitt and MonoSol have deprived Plaintiff States, government entities, and consumers the benefits of competition in violation of the federal and state antitrust laws, consumer protection laws, and unfair competition statutes.
>
> 124. As a direct and proximate result of the unlawful conduct alleged above, government entities and consumers in Plaintiff States were not and are not able to purchase, or pay reimbursements for purchases of co-formulated buprenorphine/naloxone at prices determined by a market unhindered by the impact of Defendants' anticompetitive behavior.

> Instead, they have been and continue to be forced to pay artificially high monopoly prices. Consequently, they have suffered substantial injury in their business and property, and have suffered harms to their general economies in that, *inter alia*, they have paid more and continue to pay more for co-formulated buprenorphine/naloxone than they would have paid in a competitive market.

(Am. Compl. ¶¶ 118, 119, 121, 123, 124.)

In the face of these well-pled allegations, MonoSol attempts to defeat any showing of antitrust injury through three arguments. First, it contends that even assuming MonoSol had a role in preparing or submitting the citizen petition, any alleged delay in the generic ANDAs' approval while the FDA was reviewing the petition resulted from an "'arbitrary act[] of government bureaucracy' not to grant the ANDAs earlier." (Def.'s Mem. Supp. Mot. to Dismiss 19 (citing Exxon Corp. v. Amoco Oil Co., 875 F.2d 1085, 1089 (4th Cir. 1989); Midland Export, Ltd. v. Elkem Holding, Inc., 948 F. Supp. 163, 166 (E.D. Pa. 1996).)[11] It goes on to assert that the filing of the citizen petition could not plausibly have delayed generic entry absent allegations that MonoSol influenced the length of the FDA's review of the ANDAs and Indivior's citizen petition, or allegations that the FDA exceeded the 150-day statutory period for such review.

MonoSol, however, fails to establish that the FDA action was a purely independent cause fully accountable for the alleged antitrust injury, rather than a merely intervening cause.[12] In re

---

[11] Neither of these cases supports Defendant's argument. Exxon Corp. involved a superseding government act in the context of a tort claim, not an antitrust claim. Exxon Corp., 875 F.2d at 1089. Midland Export discussed causation as one of many factors in determining whether the plaintiffs had standing to bring an antitrust suit; it did not address the requisite pleading of causation for an antitrust claim. Midland Export, 948 F. Supp. at 166.

[12] I previously addressed an identical argument on reconsideration of my decision regarding the Class Action Complaint. In re Suboxone, MDL No. 2445, 2015 WL 12910728 (E.D. Pa. Apr. 14, 2015). In that matter, Indivior argued that even if its citizen petition caused the FDA to delay approval of the generic's ANDA, the FDA's actions are a supervening cause because the generic manufacturers had failed to follow the proper FDA procedures. Id. at *2. I rejected that

Wellbutrin SR/Zyban Antitrust Litig., 281 F. Supp. 2d 751, 756 (E.D. Pa. 2003) (citing 2 Phillip E. Areeda & Herbert Hovenkamp, Antitrust Law ¶ 338b at 321 (2d ed. 2000) (noting that when a defendant relies upon the existence of an independent cause, such cause "must be examined closely to make sure that it is the independent cause, rather than the illegal antitrust action, that gives rise to the plaintiff's injury.")). "Several courts have held that a finding of antitrust injury cannot be tied to the status of FDA approval of a generic applicant." Gabapentin, 649 F. Supp. 2d 346 (citing Bristol–Myers Squibb Co. v. Ben Venue Labs., 90 F. Supp. 2d 540, 544–46 (D.N.J. 2000) (accepting the counterclaimants' contention that they need not demonstrate FDA approval in order to invoke antitrust standing); Abbott Labs. v. Mylan Pharms., No. 05-6561, 2007 WL 625496, at *4 n.2 (N.D. Ill. Feb. 23, 2007) (observing that "the structure of these statutes means that, if antitrust injury were tied to the status of FDA approval relative to the required timing of the suit, antitrust injury would be 'wholly contingent on the vagaries of timing of agency action' and go against the purpose of the Hatch–Waxman Act.") (internal citations omitted)). Thus, where a complaint alleges that a defendant has attempted to delay FDA approval in some manner, courts have held that "such conduct creates the anticompetitive effect that the antitrust laws were designed to prevent, and therefore constitutes antitrust injury." In re Neurontin Antitrust Litig., No. MDL 1479, 2009 WL 2751029, at *13 (D.N.J. Aug. 28, 2009). (citing cases).

In the present case, while MonoSol may ultimately adduce proof that the FDA's delay in the approval of the generic tablets caused the antitrust injury, they cannot, at this juncture,

---

argument, noting that although Indivior could raise supervening causation as an affirmative defense, the allegations of the complaint allowed an inference that the government's decision was induced by the defendant's deception or wrongful conduct. Id. I ultimately found that the plaintiffs had alleged sufficient facts to plausibly plead causation.

establish that it completely breaks the causal link between the alleged antitrust violation and that injury. Plaintiffs have sufficiently pled that Indivior and MonoSol's actions had the intended effect of delaying the FDA approval which, in turn, delayed the entry of generics into the market.

MonoSol's second effort to defeat causation offers the unsubstantiated argument that because prescribing physicians determined whether to prescribe the film form or the tablet (generic or brand-name) form of Suboxone to each of their patients—thereby determining whether generic substitution laws would operate on the prescription—Plaintiffs cannot complain that fewer generic tablets were sold because of the presence of film in the marketplace. This argument again misunderstands Plaintiffs' pleading burden. As emphasized above, a plaintiff need not exhaust all possible alternative sources of the injury, but need only show that a defendant's unlawful conspiracy is a "material cause" of the claimed injury. Zenith Radio, 395 U.S. at 114 n.9. Plaintiffs explicitly assert that Indivior and MonoSol engaged in a joint campaign to convert the market from tablet use to film use by making "unfounded safety concerns about the tablets" and by communicating to the medical community that single-dose or unit-dose packaging—which was the type of packaging used for film, but not tablets—was necessary to prevent potential exposure to multiple doses. (Am. Compl. ¶¶ 73–74.) Such allegations are sufficient, at this juncture, to state a plausible claim that Defendants' conduct improperly influenced physicians' prescribing decisions and, therefore, was a material cause of the claimed injury.[13]

[13] MonoSol erroneously relies on the "learned intermediary doctrine." (See Def.'s Mem. Supp. Mot. to Dismiss 20 (citing Thom v. Bristol-Myers Squibb Co., 353 F.3d 848 (10th Cir. 2003); Heindel v. Pfizer, Inc., 381 F. Supp. 2d 364 (D.N.J. 2004).) This doctrine has its origins and application solely in tort law and provides that when a drug is available only upon prescription of a duly licensed physician, the warning required is not to the general public or patient, but to the prescribing doctor. Heindel, 381 F. Supp. 2d at 382. MonoSol has not cited to

Finally, MonoSol challenges Plaintiffs' allegation that "[b]ut for [Indivior] and MonoSol's illegal conduct, generic competition to Suboxone Tablets would have been available when orphan exclusivity expired in October, 2009." (Am. Compl. ¶ 119.) It asserts that the alleged facts do not show that generic manufacturers filed their ANDAs early enough for the FDA to approve generic Suboxone tablets by the time Indivior's exclusivity expired on October 8, 2009. MonoSol further reasons that generic manufacturers could not market their tablets before the FDA approved their ANDAs, which could not be done without REMS. The Amended Complaint, however, alleges that, even if Indivior had assisted its generic competitors with their REMS, generic tablets would not have been on the market until at least May 6, 2012, three and a half years after Indivior faced loss of orphan drug exclusivity. (Def.'s Mem. Supp. Mot. to Dismiss 21.) Thus, it concludes that any loss Plaintiffs sustained due to a lack of a generic alternative to the tablet cannot be attributed to Defendants' conduct.

Again, MonoSol's argument does not entitle it to a Rule 12(b)(6) dismissal of the claims against it. Even assuming that MonoSol's reasoning holds true—a determination not appropriate on a motion to dismiss—Plaintiffs have still pled antitrust injury. Generic tablets were not approved until March 2013, meaning that MonoSol's and Indivior's actions could have plausibly caused a delay during the period from the submission of the REMS to the final approval of the ANDAs. In turn, the further delay in generic entry could have resulted in injury to Plaintiffs.

In short, I heed the Third Circuit's caution that "the existence of antitrust injury is not typically resolved through motions to dismiss." Schuylkill Energy, 113 F.3d at 417. Although Defendants may be able to prove that superseding acts have broken the chain of causation between their actions and Plaintiffs' alleged injuries, the well-pled allegations of the Amended

---

any cases in which this doctrine was applied to defeat the causal link between a monopolist's anticompetitive behavior in the drug market and a consumer's injuries.

Complaint permit the plausible inference that Defendants' alleged antitrust violation was a "material cause" of the claimed injuries. Zenith Radio, 395 U.S. at 114 n.9. As the rules of pleading require no more, I deny Plaintiffs' motion on this ground.

C. Whether the Amended Complaint Plausibly Pleads a Relevant Market

MonoSol next claims that Plaintiffs' allegations regarding the relevant product market are implausible.

To plead a monopolization claim under Section 2 of the Sherman Act, a plaintiff must, among other elements, allege a relevant product market. U.S. v. Grinnell Corp., 384 U.S. 563, 570–71 (1966). The same is true of attempted monopolization and conspiracy to monopolize claims under Section 2. Rolite, Inc. v. Wheelabrator Envtl. Sys., Inc., 958 F. Supp. 992, 996 (E.D. Pa. 1997) (citing Scher, Irving, Antitrust Adviser, 4th Ed., § 1.22, at 1–40 and 1–41). Conspiracies to restrain trade under Section 1 of the Sherman Act that are not *per se* violations of the Act involve an inquiry into "market structure designed to assess the combination's actual effect," thereby requiring relevant market to be pled with regard to a Section 1 conspiracy as well. Copperweld, 467 U.S. at 768.

A relevant product market "is defined as those 'commodities reasonably interchangeable by consumers for the same purposes.'" Tunis Bros. Co., Inc. v. Ford Motor Co., 952 F.2d 715, 722 (3d Cir. 1991) (quoting United States v. E.I. Du Pont de Nemours & Co., 351 U.S. 377, 395 (1956)). The outer boundaries of the relevant market are determined by the reasonable interchangeability of use. Queen City Pizza, Inc. v. Domino's Pizza, Inc., 124 F.3d 430, 437 (3d Cir. 1997). In other words, the alleged product market must include all commodities that are reasonably interchangeable by consumers for the same purposes. Eichorn v. AT & T Corp., 248 F.3d 131, 147 (3d Cir. 2001). Reasonable interchangeability contemplates whether two

products are roughly equivalent when put to a specific use, and considers factors such as price, use, and qualities. Id. at 437. "While there may be some degree of preference for [one product] over [an]other, either would work effectively." Allen-Myland, Inc. v. Int'l Bus. Machines Corp., 33 F.3d 194, 206 (3d Cir. 1994). Reasonable interchangeability is also indicated by cross-elasticity of demand between the product itself and substitutes for it. Queen City Pizza, 124 F.3d at 437. Cross-elasticity of demand considers whether "the rise in the price of a good within a relevant product market would tend to create a greater demand for other like goods in that market." Id. at 437–38 (quoting Tunis Bros., 952 F.2d at 722). "[I]n most cases, proper market definition can be determined only after a factual inquiry into the commercial realities faced by consumers." Queen City Pizza, 124 F.3d at 436.

Plaintiffs in this case define the relevant market as follows:

> 19. The relevant product market is any drug with co-formulated buprenorphine as the active ingredients for the treatment of opioid addiction. There are no feasible substitutes for co-formulated buprenorphine/naloxone in the pharmacological intervention of opioid dependence. This market includes Suboxone Film and Tablets and any AB-rated generics that can be substituted for them.
>
> 20. Suboxone Tablets and Suboxone Film do not exhibit significant positive price cross-elasticity of demand with any opioid dependence treatment or other product other than AB-rated generic versions of buprenorphine/naloxone tablets. Suboxone is categorized as a schedule III drug and co-formulated with an opioid antagonist to deter abuse. Until 2013, Suboxone was the only replacement maintenance therapy that could be prescribed in an office setting and taken by patients at home. By contrast, Methadone, is a Schedule II drug and must be administered in a clinic. Subutex, another opioid treatment drug marketed by Reckitt [Indivior], is not interchangeable because it lacks naloxone, the opioid antagonist that deters abuse. Zubsolv (a generic buprenorphine/naloxone tablet) and Bunavail (a generic buprenorphine/naloxone film) entered the market after generic Suboxone Tablets. Zubsolv and Bunavail are not AB-rated to the Film or Tablets.

> 21. The relevant geographic market is the United States and its territories.
>
> 22. Before October 8, 2009, Suboxone was the only co-formulated buprenorphine/naloxone opioid treatment because of its orphan drug status, so Reckitt [Indivior] enjoyed 100 percent market share in the United States and its territories. After the exclusivity period expired, Reckitt's [Indivior's] branded Suboxone products, including the Suboxone Film it introduced in September 2010, remained the sole source of co-formulated buprenorphine/naloxone until two generic manufacturers introduced generic tablets in March 2013. An additional generic tablet manufacturer was approved in September 2016. When Suboxone-branded Tablets and Film were sold alongside one another, Reckitt [Indivior] successfully converted most of the Suboxone market to its Film, for which there are no generic substitutes. After the introduction of the two generic tablet products in 2013, Reckitt's market share for co-formulated buprenorphine/naloxone dropped to 68 percent.

(Am. Compl. ¶¶19–22.)

MonoSol challenges this market definition on two grounds, neither of which I find persuasive. First, it claims that, on one hand, non-AB-rated generic Suboxone tablets are excluded from the market as a treatment that is not pharmaceutically equivalent to the brand-name Suboxone tablet, while, on the other hand, the alleged market includes Suboxone film, which is not pharmaceutically equivalent to the Suboxone tablet. MonoSol asserts that either pharmaceutical equivalence is required for reasonable substitutability—in which case there cannot be a single market combining film and tablet forms—or it is not required—in which case the relevant market cannot automatically exclude other addiction treatments that are not pharmaceutically equivalent.

I find no such inherent contradiction in the relevant market definition. The litigation and, in turn, the relevant market involve the prescription drug Suboxone—which is co-formulated buprenorphine hydrochloride and naloxone hydrochloride dehydrate—in all of its forms,

including both tablets and film. (Am. Compl. ¶ 1.) Plaintiff alleges that although Suboxone tablets and film are not AB-rated, the two products are interchangeable and Indivior actually represented to the FDA that the two formulations were "clinically insignificant." (Id. ¶ 62.) The sole reason for the lack of pharmaceutical equivalency between the two products is because film is in a different dosage form than tablets. (Id. ¶ 55.) Thus, the Amended Complaint alleges that the products are functionally interchangeable and physicians could equally prescribe either Suboxone tablets or Suboxone film to obtain the same desired effect. Any generics that are AB-rated with either of these two formulations of Suboxone, then, would appropriately have a cross-elasticity of the demand. To the extent MonoSol wishes to argue that this relevant market definition does not reflect the commercial realities, such a determination requires further factual inquiry—a task that is inappropriate at the motion to dismiss stage. See Rezin v. Blue Cross & Blue Shield of Kansas, Inc., 899 F.2d 951, 979 (10th Cir. 1990) (noting that market definition is a question of fact).

Second, MonoSol contends that the alleged relevant market improperly excludes Methadone on the basis of the mode of its administration and Subutex on the basis of a difference in active ingredients. It reasons that the operative question is not whether the drugs are administered under the same conditions in treating the conditions or have the same active ingredients, but whether the drugs produce the desired therapeutic result in treating the conditions for which they are prescribed.

My prior opinion on the Class Action Complaint addressed and rejected this precise point with respect to an almost identical definition of the relevant class, as follows:

> Plaintiffs have alleged that Suboxone is a unique product and that the relevant product market is limited to Suboxone in all of its forms and dosage strengths and its AB-rated generic bioequivalents. They further allege that "Suboxone does not

> exhibit significant, positive cross-elasticity of demand with respect to price, with any opioid dependence treatment or other product other than AB-rated generic versions of Suboxone." The complaint further explains that Suboxone is unique because it is the only opioid replacement maintenance therapy that can be prescribed in an office setting and taken by patients at home because it is categorized as a Schedule III drug and co-formulated with an opioid antagonist to deter abuse. (EP Compl. ¶¶ 153–59.) Methadone, for example, is a Schedule II drug and must be administered in a clinic. Further, Subutex, another opioid treatment drug marketed by Reckitt, is not alleged to be reasonably interchangeable because it lacks the opioid a[nta]gonist, and therefore is not recommended for maintenance therapy. I must accept these statements as true.
>
> Dismissal at the motion to dismiss stage for failure to define a relevant market is disfavored. Plaintiffs have referenced the rules of reasonable interchangeability and cross-elasticity of demand and have plausibly explained why other similar products do not fall within the relevant market. These allegations are sufficient to state a claim and survive a motion to dismiss, to the extent that a relevant market analysis is even necessary where direct evidence of monopoly power is provided.

In re Suboxone (Buprenorphine Hydrochloride and Naloxone) Antitrust Litig., 64 F. Supp. 3d 665, 713 (E.D. Pa. 2014), on reconsideration in part sub nom. In re Suboxone (Buprenorphine Hydrochloride and Naloxone) Antitrust Litig., 13-MD-2445, 2015 WL 12910728 (E.D. Pa. Apr. 14, 2015). As Plaintiffs have pled both reasonable interchangeability and cross-elasticity of demand in the current Amended Complaint, I see no reason to depart from my prior ruling that such allegations satisfy a Rule 12(b)(6) standard.

D. Whether the Amended Complaint Adequately Pleads MonoSol's Specific Intent

Specific intent is an essential element of a conspiracy to monopolize claim. Bonjorno v. Kaiser Aluminum & Chem. Corp., 752 F.2d 802, 807 (3d Cir. 1984). It means "an intent which goes beyond the mere intent to do the act." Aspen Skiing Co. v. Aspen Highlands Skiing Corp., 472 U.S. 585, 602 (1985) (quoting United States v. Aluminum Co. of Am., 148 F.2d 416, 432

(2d Cir. 1945)). "The specific intent element requires plaintiffs to plead that [the] alleged conspirators 'had a conscious commitment to [the] common scheme designed to achieve an unlawful objective, namely that of endowing . . . monopoly power." Howard Hess Dental Labs. Inc. v. Dentsply Int'l, Inc., 516 F. Supp. 2d 324, 341 (D. Del. 2007) (quoting ID Security Systems Canada, Inc. v. Checkpoint Sys., Inc., 249 F. Supp. 2d 622, 660 (E.D. Pa. 2003) (citation and internal quotations omitted)); see also In re Microsoft Corp. Antitrust Litig., 127 F. Supp. 2d 728, 731 (D. Md. 2001) (specific intent "signifies something more than willing, voluntary, and knowing participation in the illegal course of conduct. . . . It means participating in that course of conduct for the specific, shared purpose of maintaining [the] monopolies."), aff'd 309 F.3d 193 (4th Cir. 2002). In other words, the defendant must have "intended to achieve an illegal monopoly." Howard Hess, 602 F.3d at 257 (quoting Joseph P. Bauer & William H. Page, II Kintner's Federal Antitrust Law § 14.40, at 423 (2002) (footnote omitted)). "Specific intent in the antitrust context may be inferred from a defendant's unlawful conduct." Id. at 257.

MonoSol avers that Plaintiffs offer nothing more than conclusory allegations, unsupported by facts, that the introduction of Suboxone film was "intended to thwart generic entry," to "maintain [Indivior's] market share," to "avoid competition from generic entrants," to protect from "generic incursion," or to "prevent generic competition." (Am. Compl. ¶¶ 50, 63, 69, 154.) According to MonoSol, the only factual allegations in the Amended Complaint that could support these conclusions are that MonoSol and Indivior introduced a new product to compete with generic versions of the Suboxone tablet and that MonoSol marketed pharmaceutical film as a possible means for drug companies to maintain their customer base in the face of generic competition. MonoSol claims, however, that neither of these facts support a

plausible inference that it acted with the specific intent to help Indivior maintain an unlawful monopoly in the alleged relevant market.

MonoSol's argument again attempts to parse the allegations regarding MonoSol's conduct into individual actions that, taken separately, would not necessarily give rise to an inference of anticompetitive intent. As I noted previously, "a plaintiff can allege a series of actions that when taken together make out antitrust liability even though some of the individual actions, when viewed independently, are not all actionable." In re Suboxone, No. 16-563, 2017 WL 36371, at * 8 (E.D. Pa. Jan. 4, 2017) (citing Cont'l Ore Co. v. Union Carbide & Carbon Corp., 370, U.S. 690, 699 (1962) (concluding that it is improper to treat antitrust claims as "separate and unrelated lawsuits" and that "plaintiffs should be given the full benefit of their proof without tightly compartmentalizing the various factual components and wiping the slate clean after scrutiny of each"); LePage's Inc. v. 3M, 324 F.3d 141, 162 (3d Cir. 2003) ("courts must look to the monopolist conduct taken as a whole rather than considering each aspect in isolation")) (further citations omitted).

The various allegations within the Amended Complaint allow a reasonable inference that MonoSol possessed the requisite intent to help Indivior establish and maintain a monopoly through the development of Suboxone film. For example:

- MonoSol convinced Indivior to develop a film form of Suboxone and bring it to market for the purpose of extending Indivior's exclusivity in the co-formulated buprenorphine/naloxone market. (See Am. Compl. ¶¶ 46–47.)

- MonoSol's own website encouraged pharmaceutical companies to engage in anticompetitive product-hopping by allowing companies to avoid the patent claim, extend the patent life cycle for products, and avoiding generic incursion and substitution as patent expiration nears. (See id. ¶ 48.)

- MonoSol negotiated with Indivior to receive royalty payments on sales of Suboxone film, thereby incentivizing it to help Indivior achieive monopoly power and profits. (See id. ¶ 49.)

- MonoSol actively strategized with Indivior to minimize manufacturing delays to beat generic tablets to market. (See id. ¶ 54.)

- MonoSol made the initial suggestion that Indivior could withdraw Suboxone tablets from the market, thereby making a hard switch, in order to provide further protection from generic incursion. (See id. ¶ 71.)

- MonoSol actively participated in Indivior's plan to generic entry through its abuse of the citizen petition process. (See id. ¶ 112.)

Taken collectively, these allegations permit the plausible inference that MonoSol consciously committed to the common scheme of endowing illegal monopoly power on Indivior and benefitting from such monopoly power. Indeed, allegations which reference the language of its website, showing MonoSol's intent to help Indivior retain market exclusivity and prevent generic incursion, combined with its subsequent actions of (1) rushing the NDA for Suboxone film through the approval process; (2) proposing the withdrawal of the Suboxone tablet; and (3) attempting to delay generic entry through the citizen petition process, plausibly suggest that MonoSol clearly intended to do more than just compete. Such actions are probative of its conscious commitment to monopolize on behalf of Indivior. At this early stage of the litigation, Plaintiffs need allege nothing further in order to survive Rule 12(b)(6) scrutiny.

E. Whether the Sherman Act and State Law Claims Against MonoSol are Time Barred

In a fifth effort to dismiss all causes of action against it, MonoSol argues that Plaintiffs' claims are time barred. Specifically, it contends that the last alleged action by MonoSol in the Amended Complaint—the citizen petition meetings—took place as early as 2011, while Plaintiffs did not file their first complaint until September 22, 2016. As the applicable statute of limitations for the alleged Sherman Act and state causes of action is four years, MonoSol asserts that these claims are time barred.

The statute of limitations for a claim pursuant to the Sherman Act is "four years after the cause of action accrued."[14] 15 U.S.C. § 15b. Under federal antitrust law, the statute of limitations initially begins to run "when a defendant commits an act that injures a plaintiff's business." Zenith Radio, 401 U.S. at 338. The Supreme Court, however, has explained that the limitations period does not begin to run until the damages are inflicted and ascertainable, id. at 338–40, meaning that the date of the defendant's last action is not dispositive. Statutes of limitations issues "present mixed questions of law and fact." In re Lower Lake Erie Iron Ore Antitrust Litig., 998 F.2d 1144, 1171 (3d Cir. 1993). "[G]enerally the statute of limitations defense cannot be decided in the context of a Rule 12 motion, except in situations where 'the complaint facially shows noncompliance with the limitations period and the affirmative defense clearly appears on the face of the pleading.'" Chemi SpA v. GlaxoSmithKline, 356 F. Supp. 2d 495, 499 (E.D. Pa. 2005) (quotation omitted).

Under this jurisprudence, I decline to dismiss the claims as time barred. As noted above, the original Complaint in this action was not filed until September 22, 2016, meaning that to be timely, the causes of action would have had to accrue no earlier than September 22, 2012. From the face of the Amended Complaint, I am unable to determine the precise accrual date. Although MonoSol's last alleged action occurred sometime in 2011, the citizen petition—in which MonoSol purportedly had a hand—was not filed until September 25, 2012, and the withdrawal of Suboxone tablets—which allegedly occurred at MonoSol's urging—did not occur until March 18, 2013. (Am. Compl. ¶ 88, 102, 156.) It remains unclear when exactly the damages were

[14] With a citation to each of the relevant state statutes in this case, MonoSol represents that the statute of limitations for each of the state law claims is also four years. (Def.'s Mem. Supp. Mot. to Dismiss 24 n.13.) Plaintiffs, on the other hand, allege that a number of the states' statute of limitations periods do not run against claims by the State itself. (Pls.' Resp. Opp'n Mot. to Dismiss 22 n.108.) For the sake of judicial economy, I accept for purposes of this Motion only that all of the relevant state statutes have four-year statutes of limitation.

inflicted on and ascertainable by Plaintiffs. Absent sufficient facts from which I can determine an accrual date, I cannot conclusively hold that the claims against MonoSol are barred by the statute of limitations.

F. Whether the State Antitrust, Consumer Protection, and Unfair Trade Practices Claims Fail

MonoSol's final argument asserts that "Plaintiffs' state claims are deficient for a number of reasons, including, most importantly, because the state antitrust, consumer protection and unfair trade practices statutes or the case law interpreting them indicate that they should be construed in harmony with federal antitrust law." (Def.'s Mem. Supp. Mot. to Dismiss 25.) In support of its position, MonoSol relies entirely on the brief of former co-defendant RBH in support of its Motion to Dismiss.

This argument, however, fails to recognize the distinguishing factors between MonoSol and RBH. In granting RBH's Motion to Dismiss the state law claims, I found that because the federal antitrust law claims against RBH failed, the claims under state antitrust, consumer protection, and unfair trade practice statutes—statutes which are interpreted consistently with the federal antitrust laws—could not survive. In re Suboxone, No. 16-5073, 2017 WL 4642285, at *11–13 (E.D. Pa. Oct. 17, 2017). In contrast, however, the federal antitrust claims against MonoSol are not deficient, meaning that similar state law claims could conceivably withstand a similar Rule 12(b)(6) review. Absent further argument by MonoSol, I will not dismiss these claims.

IV. CONCLUSION

Plaintiffs have pled plausible causes of action against Defendant MonoSol for conspiracy to monopolize under Sherman Act § 2, illegal restraint of trade under Sherman Act § 1, and

various state law antitrust, unfair trade practices, and consumer protection statutes. Accordingly, I will deny MonoSol's Motion to Dismiss in its entirety.

An appropriate Order follows.